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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 93

[Docket No. APHIS-2008-0112]

RIN 0579-AD31

Importation of Horses from Contagious Equine Metritis-Affected Countries

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are adopting as a final rule, with changes, an interim rule that amended the regulations regarding the importation of horses from countries affected with contagious equine metritis (CEM) by incorporating an additional certification requirement for imported horses 731 days of age or less and adding new testing protocols for test mares and imported stallions and mares more than 731 days of age. This document revises certain CEM-testing requirements for imported stallions and mares, and for test mares, that were amended in the interim rule. The interim rule was necessary to provide additional safeguards against the introduction of CEM through the importation of affected horses.

EFFECTIVE DATE: [Insert date 30 days after publication in the Federal Register].

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## SUPPLEMENTARY INFORMATION:

### Background

The regulations in 9 CFR part 93 (referred to below as the regulations) prohibit or restrict the importation of certain animals into the United States to prevent the introduction of communicable diseases of livestock. Subpart C—Horses, §§ 93.300 through 93.326, pertains to the importation of horses into the United States. Sections 93.301 and 93.304 of the regulations contain specific provisions for the importation of horses from regions affected with contagious equine metritis (CEM), which is a highly contagious venereal disease of horses and other equines caused by infection or contamination with the bacterium Taylorella equigenitalis.

In an interim rule<sup>1</sup> effective and published in the Federal Register on March 25, 2011 (76 FR 16683-16686, Docket No. APHIS-2008-0112), we amended the regulations in § 93.301 regarding the importation of horses from countries affected with CEM by incorporating an additional certification requirement for imported horses 731 days of age or less and adding new testing protocols for test mares and imported stallions and mares more than 731 days of age.

We solicited comments concerning the interim rule for 60 days ending May 24, 2011. In response to implementation concerns raised by commenters, we published a document in the Federal Register on May 31, 2011 (76 FR 31220-31221, Docket No. APHIS-2008-0112), in which we announced that we were delaying enforcement of the interim rule until July 25, 2011, in order to provide CEM testing facilities time to make necessary adjustments to their operating procedures for the rule to be successfully implemented. In a subsequent document published in the Federal Register on August 23, 2011 (76 FR 52547-52548, Docket No. APHIS-2008-0112),

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<sup>1</sup> To view the interim rule, the two documents delaying enforcement, and the comments we received, go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2008-0112>.

we announced that the delay of enforcement would continue until the publication of a final rule, and reopened the comment period until September 7, 2011.

We received a total of 18 comments by that date. They were from private citizens, foreign governments and commission, State departments of agriculture, a State veterinary agency, and U.S. horse organizations. Seventeen of the commenters agreed that additional safeguarding measures were warranted to protect the U.S. horse industry; however, those commenters did not agree with certain aspects of the changes made in the interim rule. The comments are discussed by topic below.

#### Imported Mares

The March 2011 interim rule contained a new requirement that mares over 731 days of age imported from a CEM-affected region be given a complement fixation (CF) test at the post-arrival CEM quarantine facility. A few commenters suggested that we allow the blood to be taken and the CF test to be completed at the port of entry rather than at the post-arrival quarantine facility in order to reduce the post-arrival quarantine period.

While we understand the commenters' concern regarding import delays and convenience, we believe that since the CF test on imported mares is a component of the CEM testing program, the blood sample must be taken and the test completed at a CEM quarantine facility. CEM testing, including CF testing, is a separate function from import quarantine testing, requirements for which are contained in 9 CFR 93.308. Ports are not equipped or staffed to provide CEM testing services that are available at designated CEM quarantine facilities.

In any case, we believe the commenters' concern is unwarranted. Collecting and submitting a blood sample at CEM quarantine facilities will not add any time to the CEM

quarantine, since CF test results would be available before the mare has finished the culture and treatment phase of CEM testing.

One commenter stated that we needed to clarify the procedure for imported mares that test positive for CEM. The commenter asked whether the positive mare would be returned to the country of origin or treated at the quarantine facility.

Imported mares that test positive for CEM are not returned to their country of origin. Rather, as provided under § 93.301(e)(5), imported mares that test positive for CEM are treated and retested.

One commenter stated that it was important to identify pregnant and nonpregnant mares due to the difference in testing requirements for each. The commenter asked whether there was a declaration required to identify pregnant and nonpregnant mares and, if so, whether the declaration is confirmed by an accredited veterinarian.

Mares over 731 days of age are accompanied at the time of importation by an import health certificate, but the health certificate does not include the breeding status of the mare. Our expectation, however, is that the owner, importer, or agent will tell the veterinarian in the United States or the exporting country the breeding status of the mare and that the veterinarian will test accordingly. We recommend that accredited veterinarians performing CEM testing at the post-entry quarantine facility examine mares by rectal palpation or ultrasound to determine the breeding status as part of their standard operating procedures.

#### Imported Stallions

Previously, § 93.301(e)(3)(i) required stallions to be cultured for CEM and test bred to two test mares after negative results from the cultures are obtained. The March 2011 interim rule amended that requirement to require that, prior to test breeding, three sets of cultures be collected

from imported stallions rather than one set. The interim rule allowed test breeding to take place only after the first two sets of cultures had yielded negative results.

Some commenters questioned the necessity of collecting more than one set of pre-breeding cultures from imported stallions. One commenter recommended taking post-breeding cultures.

We are making a change to the final rule based on these comments and the 2007 CEM Program Review, which determined that test breeding is a more sensitive test for CEM than pre-breeding cultures. This final rule amends paragraph (e)(3)(i) of § 93.301 to require that one set of cultures be collected from the stallion prior to breeding with negative results, consistent with our previous regulations. A stallion may be released from State quarantine only if all cultures and tests of specimens from the mares used for test breeding are negative for CEM and all cultures performed on specimens taken from the stallion are negative for CEM. If any culture or test is positive for CEM, the stallion would be treated for CEM as described in § 93.301(e)(3)(i)(A) and retested by being test bred to two mares no less than 21 days after the last day of treatment. Given the interim rule's enhancements to the testing process for test mares, we believe that requiring one set of cultures to be taken from imported stallions will be sufficient to prevent the introduction of CEM.

One commenter stated that we needed to clarify whether stallions must be treated for CEM at quarantine facilities regardless of test results.

As stated in § 93.301(e)(3)(i), upon completion of the test breeding, stallions must be treated for 5 consecutive days in accordance with paragraph (e)(3)(i)(A) of § 93.301, regardless of their test status. If a test mare cultured for CEM shows positive results, then the stallion is treated again and retested. A stallion may be released from State quarantine only if all cultures

and tests collected from test mares are negative for CEM and all cultures and tests collected from the stallion are negative for CEM.

#### Test Mares

The March 2011 interim rule required three sets of cultures to be taken from the distal cervix or endometrial of test mares. One commenter questioned whether three sets of distal cervix or endometrial cultures from test mares would be an effective method for detecting CEM because of the potential of overgrowth and contamination of the second and third set of cultures. This would result in repeat cultures which would increase the cost and time of the post-arrival quarantine process. The commenter suggested that cultures from the distal cervix or endometrial be collected on the third set of cultures only.

We agree with the commenter and are making a change to the interim rule as a result. Specifically, we are no longer requiring that cultures from the distal cervix or endometrium be included with all three sets of cultures collected from the test mares. Instead, paragraphs (e)(3)(i)(B) and (e)(4)(ii) of § 93.301 now require that only the third set of cultures include a swab from the distal cervix or endometrium. In addition, we are amending paragraph (d)(1)(ii)(D), which contains similar requirement for the importation of Spanish Pure Breed horses and thoroughbred horses over 731 days, to require that only the third set of cultures from imported mares include a swab from the distal cervix or endometrium.

The interim rule required CF testing to be completed for test mares on the twenty-first day after breeding. One commenter asked what date range would be acceptable if the blood test for the CF testing could not be done exactly on day 21. The commenter stated that the date range for the completion of the CF test needs to be spelled out due to weekends, scheduling, and operation status of the laboratories.

We agree with this comment. If a test mare becomes CEM positive after breeding, the CF test titer begins to rise at day 15 post breeding, and would be expected to continue rising between days 21 and 28. Therefore, we are amending paragraph (e)(3)(i)(B) of § 93.301 to state that a CF test for CEM must be done with negative results between the twenty-first and twenty-eighth day after the breeding. This change will provide additional flexibility in test scheduling, without compromising the ability to detect infection.

Exemptions: Geldings and Horses 731 Days of Age or Younger

The regulations in paragraph (c)(2) of § 93.301 exempts recently castrated stallions (geldings) from CEM-related importation requirements. Several commenters suggested that geldings be tested and treated for CEM, as recommended by the 2007 CEM Program Review. A concern was expressed that recently castrated stallions could maintain stallion-like behavior and attempt and achieve intromission with mares in estrus, thereby creating a risk for CEM transmission.

Geldings will not be used for breeding purposes, which is where the risk of CEM transmission is greatest. We do not believe that the possibility of incidental contact between a gelding and an in-season mare warrants the additional time and expense associated with CEM testing and treatment for geldings.

The regulations also exempt weanlings or yearlings whose age is certified on the import health certificate. One commenter suggested that newborn colts from CEM-infected mares should be tested and treated for CEM. In addition, the commenter suggested that all weanlings and yearlings be tested and treated for CEM as there is evidence that non-venereal transmission is possible.

We acknowledge that it is possible for a foal to be born with CEM if the dam was infected; however, the risk of non-venereal transmission of CEM is low and does not justify testing and treating imported weanlings and yearlings that have not been bred.

One commenter stated that some cryptorchid stallions look like geldings and, therefore, all geldings should be tested to ensure no stallions that might be misidentified are admitted into the United States.

Each horse is accompanied at the time of importation by an import permit issued in accordance with § 93.304. We acknowledge that it is possible for a stallion to be misidentified; however, the risk is low and does not justify testing and treating every male horse that is imported into the United States.

One commenter asked how we regulate imported mares 731 days of age or younger that are determined to be pregnant.

If an imported mare 731 days of age or younger is pregnant upon arrival to the port of entry, the mare will be tested and treated in accordance with § 93.301(e).

One commenter asked why competition horses are tested if they are not used for breeding.

As stated in § 93.301(f), horses temporarily imported into the United States for competition or entertainment purposes are not subject to CEM testing upon entry. Stallions and mares imported for permanent entry into the United States must be tested for CEM even if importers plan to use those horses solely for competition at the time of import because the horses may be used for breeding after competition.

One commenter asked that we clarify the required testing protocols for each category of horse imported into the United States. Specifically, the commenter wanted clarification whether



horses temporarily imported for competition are exempt from post-arrival quarantine, while horses temporarily imported for entertainment purposes are now subject to the post-arrival quarantine.

Horses imported into the United States temporarily under § 93.301(f) for either competition or entertainment purposes are not required to be tested for CEM in the United States. Horses entering temporarily for entertainment purposes must be tested in the country of origin. Horses entering temporarily for competition for periods of 90 days or less do not need to be tested in the country of origin. Mares and stallions imported permanently must be tested in the United States and in the country of origin.

#### Miscellaneous

A few commenters suggested that we address the recommendations presented in the 2007 CEM Program Review regarding oversight, asking that we establish minimum standards for quarantine facilities, testing protocols, and recordkeeping. The commenters suggested that we conduct regular training of testing officials and make unscheduled visits to animal import centers, quarantine facilities, and labs to review each facility's compliance with the regulations.

We cooperate with State officials to ensure compliance and accountability at each facility. At present, we are drafting a policy document that provides minimum standards of operation for each stage of the post-arrival quarantine process. We have conducted training courses for testing officials and laboratory personnel, and will conduct training in the future as resources become available. Therefore, it is not necessary to amend the regulations by adding minimum standards for quarantine facilities, testing protocols, and recordkeeping.

One commenter asked if there was a system in place to ensure that horses imported under temporary status for competition exit the country after the completion of their competition and that they are not used for breeding purposes during their stay.

As stated in § 93.301(f), any horse temporarily imported would be monitored by the Animal and Plant Health Inspection Service (APHIS) to ensure that the horse is moved according to the itinerary and methods of transport specified by the import permit. The regulations clearly state that a horse imported temporarily for competition or entertainment must not be used for breeding. If an owner or importer subsequently seeks permission to keep the horse in the United States, the horse would be transported to a State quarantine facility to undergo the post-arrival quarantine testing and treatment procedures.

A commenter inquired about the CEM testing and treatment requirements for horses being exported. The commenter stated that requiring exporters to test and treat horses prior to exportation, particularly if that horse has never tested positive for CEM, is an unnecessary burden on exporters and results in a loss of sales.

Export testing requirements are determined by the destination country, not by APHIS. Thus, exporters must test and treat horses prior to exportation as required by the destination country.

One commenter stated that APHIS' list of CEM-affected countries in § 93.301 is different from the list established by Canadian officials.

APHIS considers a country CEM-affected when CEM has been reported in that country or where free movement of horses from CEM-affected regions is allowed. APHIS will add additional countries to the list of CEM-affected regions when evidence is available that the organism is present in those countries, or when a country reports the disease to the World

Organization for Animal Health. Canada uses a different approach for determining countries from which imported horses must be tested for CEM, and Canada's list includes countries that have not reported CEM.

One commenter recommended that we require horses with a history of residing in a CEM-affected country for more than 30 days to be tested for CEM, even if they have resided in a CEM-free country for 12 or more months prior to exportation.

Our current regulations only require CEM testing if a horse has resided in a CEM-affected region during the 12 months prior to importation. We acknowledge that there may be some benefit to testing horses that have resided in a CEM-affected region at any time prior to importation, especially if the horse has not been adequately tested and found free of CEM after importation into a CEM-free region. We are considering a future action to amend the regulations accordingly.

One commenter recommended that we provide detailed pictures of the sites required to be cultured for CEM testing since the nomenclature for these test sites differs between countries.

We recognize that each country has its own system of identifying the required culture sites. We cannot include color pictures within the regulations, which are essential for accurately identifying the culture sites. However, we provide that information in policy documents and on our Web site.<sup>2</sup>

Paragraph (e)(1)(iii) of § 93.301 provides the testing requirements for horses prior to exportation from their country of origin. We neglected to amend this paragraph in the interim rule by adding the additional culture sites for stallions and mares that the interim rule required for horses tested in domestic CEM quarantine. Therefore, we are amending § 93.301(e)(1)(iii) by adding the distal urethra as a culture site for stallions and the distal cervix or the endometrium

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<sup>2</sup> For more information, go to [http://www.aphis.usda.gov/import\\_export/animals/live\\_animals.shtml](http://www.aphis.usda.gov/import_export/animals/live_animals.shtml).

as a culture site for mares imported into the United States. The addition of the culture sites will make the regulations consistent with the changes made in the interim rule.

Therefore, for the reasons given in the interim rule and in this document, we are adopting the interim rule as a final rule, with the changes discussed in this document.

This final rule also affirms the information contained in the interim rule concerning Executive Order 12866 and the Regulatory Flexibility Act, Executive Orders 12372 and 12988, and the Paperwork Reduction Act.

Further, this action has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

#### Regulatory Flexibility Act

This final rule follows an interim rule that amended the regulations regarding the importation of horses from countries affected with CEM by incorporating an additional certification requirement for imported horses 731 days of age or less and adding new testing protocols for test mares and imported stallions and mares more than 731 days of age.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is summarized below, regarding the economic effects of this rule on small entities. Copies of the full analysis are available on the Regulations.gov Web site (see footnote 1 in this document for a link to Regulations.gov) or by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

The final regulatory flexibility analysis examines expected impacts for U.S. small entities of amending the regulations under which stallions and mares are imported from CEM-affected countries. For an importer of a mare from a CEM-affected country, we expect the additional

costs will range from \$80 to \$255. For an importer of a stallion from a CEM-affected country, we expect the additional costs will range from \$620 to \$830.

Currently, CEM testing costs vary by State and within State, averaging about \$1,760 for mares and \$5,070 for stallions. The overall impact of the additional costs for the horse industry is not expected to be significant, given the relatively small number of horses imported from CEM countries (less than 2 percent of imports). The additional costs are also not large when compared to expected benefits in terms of reduced risk of a CEM outbreak in the United States.

#### List of Subjects in 9 CFR Part 93

Animal diseases, Imports, Livestock, Poultry and poultry products, Quarantine, Reporting and recordkeeping requirements.

Accordingly, the interim rule amending 9 CFR part 93 that was published at 76 FR 16683-16686 on March 25, 2011, is adopted as a final rule with the following changes:

#### PART 93--IMPORTATION OF CERTAIN ANIMALS, BIRDS, FISH, AND POULTRY, AND CERTAIN ANIMAL, BIRD, AND POULTRY PRODUCTS; REQUIREMENTS FOR MEANS OF CONVEYANCE AND SHIPPING CONTAINERS

1. The authority citation for part 93 continues to read as follows:

Authority: 7 U.S.C. 1622 and 8301-8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

2. Section 93.301 is amended as follows:

- a. By revising the first sentence of paragraph (d)(1)(ii)(D); and
- b. By revising paragraphs (e)(1)(iii), (e)(3)(i) introductory text, (e)(3)(i)(B), and (e)(4)(ii).

The revisions read as follows:

§ 93.301 General prohibitions; exceptions.

\* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) \* \* \*

(D) For Spanish Pure Breed horses and thoroughbred horses over 731 days of age, cultures negative for CEM were obtained from three sets of specimens collected within a 12-day period from the mucosal surfaces of the clitoral fossa and the clitoral sinuses, with one set of specimens including a specimen from the surfaces of the distal cervix or endometrium, of any female horses and from the surfaces of the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis, of any male horses. \* \* \*

\* \* \* \*

(e) \* \* \*

(1) \* \* \*

(iii) A set of specimens must be collected from each horse within 30 days prior to the date of export by a licensed veterinarian who either is, or is acting in the presence of, the veterinarian signing the certificate. For stallions, the set of specimens consists of one culture swab from each location shall be taken from the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis; for mares, the specimens must be collected from the mucosal surfaces of the clitoral fossa, clitoral sinuses, and the distal cervix or endometrium in nonpregnant mares. All of the specimens collected must be cultured for CEM with negative results in a laboratory approved to culture for CEM by the national veterinary service of the region of origin;

\* \* \* \* \*

(3) \* \* \*

(i) Once the stallion is in the approved State, one specimen each shall be taken from the prepuce, the urethral sinus, the distal urethra, and the fossa glandis, including the diverticulum of the fossa glandis, of the stallion and be cultured for CEM. After negative results have been obtained, the stallion must be test bred to two test mares that meet the requirements of paragraph (e)(4) of this section. Upon completion of the test breeding:

\* \* \* \* \*

(B) Each mare to which the stallion has been test bred shall be cultured for CEM from three sets of specimens from the mucosal surfaces of the clitoral fossa and clitoral sinuses, with one set of specimens including a specimen from either the distal cervix or endometrium, between the third and fourteenth day after breeding, with negative results. The sets of specimens must be collected on three separate occasions within a 12-day period with no less than 72 hours between each set. A complement fixation test for CEM must be done with negative results between the twenty-first and twenty-eighth day after the breeding.

\* \* \* \* \*

(4) \* \* \*

(ii) The test mares must be qualified prior to breeding as apparently free from CEM and may not be used for breeding from the time specimens are taken to qualify the mares as free from CEM. To qualify, each mare shall be tested with negative results by a complement fixation test for CEM, and specimens taken from each mare shall be cultured negative for CEM. Sets of specimens shall be collected on three separate occasions from the mucosal surfaces of the clitoral

fossa and the clitoral sinuses, with one set of specimens including a specimen from either the distal cervix or endometrium, within a 12-day period with no less than 72 hours between each set.

\* \* \* \* \*

Done in Washington, DC, this 6<sup>th</sup> day of February 2013.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2013-03024 Filed 02/08/2013 at 8:45 am; Publication Date: 02/11/2013]